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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,497	07/20/2007	Stanton R. Canter	NOBELB.257NP	8330

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EXAMINER

MORAN, EDWARD JOHN

ART UNIT	PAPER NUMBER
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3732

NOTIFICATION DATE	DELIVERY MODE
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03/03/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/587,497	Applicant(s) CANTER, STANTON R.	
	Examiner Edward Moran	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/24/09 5/27/09
1/23/09 7/25/08 12/18/07 1/30/07.

DETAILED ACTION

Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

1. The disclosure is objected to because of the following informalities:

2. On page 4, paragraph [0016], the specification states that “Fig. 2 is a plan view of the distal end of the anchoring element”. However, Figure 2 appears to be a view of the proximal end of the anchoring element and Figure 3 being a view of the distal end.

3. On page 7, paragraph [0053], the specification states that “the proximal end is the end to the upper right” with regards to Figure 1, however, Figure 1 appears to show the proximal end to the upper left, and distal end to the lower right.

Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1–20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 11/035266. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting application provides narrower and more specific claims for the same invention, that merely explain the invention more clearly than the recited claims. The conflicting claims can easily read on the presented claims in this application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 11-13 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Niznick (US Patent 5622500).

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8. Regarding claims 1-3, 11-13 and 20, Niznick teaches an anchoring element (204) comprising a first surface with exterior threads (bottom-left implant of Figure 6), a distal end (bottom portion) and a proximal end (top portion), an abutment surface at the proximal end situated at a perpendicular angle to the longitudinal axis of the implant, an annular second surface on the bottom of the implant since the implant is disclosed as cylindrical (column 3, lines 62-63), a third surface (circumferential wall portion of the inner passage shown at the distal end of implant 204) concentric with the first surface, and a fourth surface (top surface of the distal inner passage). Niznick also shows the distal portion of the first surface as being tapered having the end with the smaller circumference closer to the distal end, as well as the third surface being tapered so that the end with the larger circumference is adjacent to the distal end as shown in Figure 6. The method of claim 20 contains essentially the same limitations and structure of the preceding claims, and since Niznick teaches the structure, it also teaches the method

9. Claims 1-3, 6-9 and 11-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Lazarof (US Patent Application Publication 2005/0042574).

10. Regarding claims 1-3, 6-9 and 11-20, Lazarof teaches an anchoring element (Fig. 2) comprising a first surface with exterior threads (12), a distal end (rightmost portion of Fig. 2) and a proximal end (leftmost portion of Fig. 2), an abutment surface near the proximal end situated at an angle to the implant, an annular second surface on the bottom of the implant (distal end), a third surface that is concentric with the first surface (circumferential wall portion of the inner passage shown extending from the distal end of the implant), a fourth surface which is shown as the top surface of the

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distal inner passage between the circumferential wall of the third surface and the circumferential wall of a fifth surface (threaded wall of shank 7), and a sixth surface located at the tip of the shank 7 (distal end). The first surface is showed to be tapered in Fig. 2, with the narrower portion closer to the distal end, and the third surface is also showed to be tapered (in Figs. 2 and 3), with the wider portion closer to the distal end. Fig. 7 shows an embodiment with an inner shank whose outside surface defines the fifth surface which is shown to include a conical portion adjacent the distal end. Figure 2 of Lazarof also shows the first, second, third and fourth surface located on a first part (the outer shell of the implant in Fig. 2), the fifth and sixth surfaces located on a second part (i.e. the threaded shank 7), and also shows the second part passing through the first part. Figure 7 further shows the anchoring element as described in claim 8, but further shows that the fourth surface can be included on the second part. Lazarof further shows means (e.g. the first and second surfaces from above) for bearing against a first surface of bone that are capable of compressing the bone and threaded for cutting when pressed against it, and additionally a fifth means (circumferential threaded sides of shank 7) that is capable of bearing against a side wall of a prepared hole, which can also compress and threadably engage the bone in the side of the hole. The method of claim 20 contains essentially the same limitations and structure of the preceding claims, and since Lazarof teaches the structure, it also teaches the method.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niznick in view of Eibes et al (US Patent 3866510).

14. Regarding claims 4 and 5, Niznick discloses the anchoring element from above, but fails to show the third surface including an internal thread.

15. Eibes et al, however, discloses a cylindrical bushing (Fig. 6) with identical external and internal threads (B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Niznick's anchoring element to include internal threads to the third surface to match those of the first surface in order to retain the self-tapping property of the device as taught by Eibes et al.

16. Claims 4-5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarof in view of Eibes et al.

17. Regarding claims 4-5 and 10, Lazarof discloses the anchoring element described above, but fails to show the third surface including an internal thread.

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18. Eibes et al, however, discloses a cylindrical bushing (Fig. 6) with identical external and internal threads (B). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Lazarof's anchoring element to include internal threads to the third surface to match those of the first surface in order to retain the self-tapping property of the device as taught by Eibes.

Additionally, it is important for all the threaded surfaces to have approximately the same pitch so as to maintain a proper self-tapping configuration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Moran whose telephone number is (571)270-5349. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571)272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. M./
Examiner, Art Unit 3732
2/23/2010

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732